

In the Claims

1. (previously presented) A stabilized lyophilized hepatitis A live vaccine formulation comprising prophylactically effective titers of live attenuated hepatitis A virus and a stabilizer, wherein said live attenuated hepatitis A virus is prepared from the wild-type HAV, strain L-A-I, and wherein said stabilizer is present in the vaccine formulation at a concentration sufficient to stabilize the hepatitis A virus against heat inactivation.

2. (canceled)

3. (previously presented) A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said stabilizer for lyophilized live hepatitis A virus comprises human serum albumin or gelatin or both of them; trehalose; at least one amino acid selected from the group consisting of glutamic acid, aspartic acid, arginine, lysine, and alkali metal salts of any of the foregoing; ascorbic acid; urea; mannitol or sorbitol or both of them; and inositol.

5. (previously presented) A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said stabilizer for the lyophilized live virus comprises from 0 to 20 grams per liter of human serum albumin, from 5 to 10 grams per liter of gelatin, from 50 to 100 grams per liter of trehalose, from 7.5 to 15 grams per liter of sodium glutamate, from 0.5 to 5.5 grams per liter of ascorbic acid, from 5 to 28 grams per liter of urea, from 2 to 10 grams per liter of mannitol or sorbitol, and from 4 to 10 grams per liter of inositol.

6. (previously presented) A method of preparing stabilized lyophilized live hepatitis A vaccine formulation according to claim 1, comprising:

(a) providing a stock suspension of attenuated live Hepatitis A virus, wherein said live attenuated hepatitis A virus is prepared from the wild-type HAV, strain L-A-I;

(b) adding a stabilizer solution to stock suspension of attenuated live hepatitis A virus obtained from step (a) at the ratio 1:1 (v/v) to obtain a live vaccine formulation comprising

prophylactically effective titers of live attenuated hepatitis A virus and a stabilizer for attenuated live virus, wherein said stabilizer comprises gelatine; trehalose; at least one amino acid selected from the group consisting of glutamic acid, aspartic acid, arginine, lysine, and alkali metal salts of any of the foregoing; ascorbic acid; urea; mannitol or sorbitol or both of them; and inositol; and

(c) lyophilizing said vaccine formulation obtained from the step (b).

7. (previously presented) A stabilizer for lyophilized live virus, wherein said stabilizer comprises gelatin; trehalose; at least one amino acid selected from the group consisting of glutamic acid, aspartic acid, arginine, lysine, and alkali metal salts of any of the foregoing; ascorbic acid; urea; mannitol or sorbitol or both of them; and inositol.

8. (previously presented) A stabilizer according to claim 7, wherein said stabilizer comprises from 0 to 20 grams per liter of human serum albumin, from 5 to 10 grams per liter of gelatin, from 50 to 100 grams per liter of trehalose, from 7.5 to 15 grams per liter of sodium glutamate, from 0.5 to 5.5 grams per liter of ascorbic acid, from 5 to 28 grams per liter of urea, from 2 to 10 grams per liter of mannitol or sorbitol, and from 4 to 10 grams per liter of inositol.

11. (original) The method according to claim 6, wherein said lyophilizing step comprises pre-cooling the vaccine formulation to about -20° C to -50° C for about 3 to 6 hours, then drying the live vaccine formulation by gradually increasing the temperature to at least 32° C in a lyophilizer.

12. (original) A stabilizer according to claim 7, wherein said lyophilized live virus is selected from the genus Enterovirus.

Claims 13-15 (canceled)

16. (currently amended) The method according to claim 6, wherein said stabilizer

comprises wherein-said-stabilizer-comprises—from 0 to 20 grams per liter of human serum albumin, from 5 to 10 grams per liter of gelatin, from 50 to 100 grams per liter of trehalose, from 7.5 to 15 grams per liter of sodium glutamate, from 0.5 to 5.5 grams per liter of ascorbic acid, from 5 to 28 grams per liter of urea, from 2 to 10 grams per liter of mannitol or sorbitol, and from 4 to 10 grams per liter of inositol.

17. (canceled)

18. (previously presented) The method according to claim 16, wherein said lyophilizing step comprises pre-cooling the vaccine formulation to about -20° C to -50° C for about 3 to 6 hours, then drying the live vaccine formulation by gradually increasing the temperature to at least 32° C in a lyophilizer.

19. (canceled)